REMARKS

The final office action that was mailed September 23, 2008, allowed claim 38, objected to claim 19 as being dependent upon a rejected base claim, and rejected claims 1-4, 7-18, 20-21, 24, 26, 29, 32-34, 36, and 37. Applicants have amended claims 1, 12, 24, 26, 29, 32-34 and 37 to more particularly define the subject matter sought to be patented, have added new claim 41, and have canceled without prejudice claims 10 and 11. The amendments add no new matter. Claims 1-4, 7-9, 12-21, 24, 26, 29, 32-38, and 40-41 are pending, with claims 35 and 40 being withdrawn as drawn to non-elected subject matter. Applicants request reconsideration in view of the amendments above and the following remarks.

Claim Rejections – 35 U.S.C. § 102

Claims 32-34 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,353,800 to Pohndorf ("Pohndorf"). Applicants have amended each of claims 32-34 to recite a half power point for the low pass filter formed by the pressure transmission catheter containing the pressure transmission fluid and barrier. The amendments add no new matter and are fully supported by the original specification (e.g., at FIG. 10 and a paragraphs [0077]-[0078], [0081]-[0082], and [0084]-[0086]).

Claim 32 is patentable over Pohndorf because Pohndorf does not disclose or suggest an implantable pressure sensing device including a pressure transmission catheter with a pressure transmission fluid and a barrier to retain the fluid, wherein the pressure transmission catheter containing the pressure transmission fluid and barrier collectively act as a low-pass filter with a half power point of approximately 10 Hz. By contrast, Pohndorf discloses a device that has "a flat frequency response in the range between zero and approximately twenty hertz." *See* column 4, lines 50-56. Indeed, Pohndorf teaches away from claim 32 by disclosing that "[i]deally, . . ., it would be preferable . . . to have a flat frequency response from at least zero to one-hundred hertz," *see* column 4, lines 48-50, a frequency ten times higher than the frequency recited in claim 32.

Neither is claim 32 obvious in view of Pohndorf, especially because Pohndorf lacks any teaching or suggestion that design features or parameters, such as the claimed pressure transmission fluid and barrier, may be selected to achieve a device with desired filtering properties.

For at least these reasons, claim 32 is patentable over Pohndorf, as are dependent claims 33-34, and Applicants request removal of the anticipation rejections to these claims.

Claim Rejections – 35 U.S.C. § 103

Claim 1

Claims 1-4, 9, 13, 15, 21, and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,846,191 to Brockway et al. ("Brockway '191") in view of U.S. Patent No. 6,592,656 to Twardowski ("Twardowski"), or alternatively in view of U.S. Patent No. 5,798,055 to Picha ("Picha"). Of these, claim 1 is independent. The Examiner also rejected dependent claims 7-8, 10-12, 14, 16-18, and 20, which depend either directly or indirectly from claim 1, under U.S.C. § 103(a) as being unpatentable over Brockway '191 in view of Twardowski or alternatively Picha, and various other secondary references.

Applicants have amended claim 1 to recite a fully implantable pressure sensing device that includes a housing configured for implantation within a body of a patient, and a pressure sensor disposed within the housing. The device also includes a polyurethane pressure transmission catheter that defines a lumen extending therethrough, the polyurethane pressure transmission catheter having a proximal portion, a mid portion, a distal portion, and a port at a distal longitudinal end of the distal portion, the proximal portion of the catheter connected to the housing, and the lumen in fluid communication with the pressure sensor, and a pressure transmission fluid disposed in the lumen. The device further includes a barrier disposed proximate the port to retain the fluid in the lumen, wherein pressure is referred from a target site within the body of the patient to the pressure sensor through the barrier and via the pressure transmission fluid, and a surface modification on an outside surface of the distal portion of the catheter, wherein the surface modification comprises a layer of material comprising a tube that does not cover the port, wherein the tube is bonded to an external surface of the distal portion of the catheter by an adhesive that provides a transition from the surface modification tube to the

external surface of the distal portion of the polyurethane catheter to reduce thrombus formation at the interface. The amendments add no new matter and are fully supported by the original specification (e.g., at paragraphs [0035] through [0044], and at FIGs. 3, 4A-4E, and 5A-5W and the corresponding discussion).

Applicants discussed Brockway '191 and Twardowski in the previous office action response. Picha discloses an open-celled polymeric foam that surrounds a distal end of a catheter to enhance fixation of the catheter in a soft tissue location. *See* col. 5, lines 1-6, 37-45.

Claim 1, as amended, is patentable over Brockway '191, Twardowski, Picha, the combination of Brockway '191 and Twardowski and the combination of Brockway '191 and Picha, because each of the references or combinations of references fails to disclose or suggest a fully implantable pressure sensing device that includes "a surface modification on an outside surface of the distal portion of the catheter, the surface modification configured to promote tissue in-growth at a blood interface, wherein the surface modification comprises a layer of material comprising a tube that does not cover the port, wherein the tube is bonded to an external surface of the distal portion of the catheter by an adhesive that provides a transition from the surface modification tube to the external surface of the distal portion of the polyurethane catheter to reduce thrombus formation at the interface." Because the surface modification tube does not cover the pressure sense port, pressure referred from a target site to the pressure sensor through the port will not be compromised by the surface modification. Also, because the surface modification tube is bonded to an external surface of the distal portion of the catheter by an adhesive that provides a transition from the surface modification tube to the external surface of the distal portion of the polyurethane catheter, a controlled healing response that includes tissue ingrowth into the tube at a blood interface where the distal portion of the catheter enters a vessel, reduced tissue in-growth across the transition because of the adhesive, and minimal or no tissue in-growth across the port, may be realized. This may provide accurate and uncompromised pressure measurements as well as reduced risk of a dangerous thrombosis.

In particular, the references fail to disclose or suggest a surface modification that comprises a layer of material comprising a tube that does not cover the port, wherein the tube is bonded to an external surface of the distal portion of the catheter by an adhesive that provides a transition from the surface modification tube to the external surface of the distal portion of the

polyurethane catheter. By contrast, the Picha foam is not a tube, and completely surrounds the distal end of the catheter, covering orifices of the device as shown in FIG. 8. As such, blood sensed by the Picha sensor 52 must first pass through the foam 42 to reach the orifices 40 of the catheter. Picha discloses sensing for oxygen, blood sugar, or pH. *See* column 5, lines 37-42. These sensed blood concentration quantities and corresponding systems are very different from the claimed pressure sensing device with a pressure sense port where pressure is referred through the port, and amended claim 1 recites that the surface modification does not cover the port. This may preserve fidelity of sensitive pressure readings and avoid compromising said readings, for example, by encouraging targeted tissue in-growth at a blood interface site where a distal portion of the catheter enters a vessel, but discouraging tissue in-growth over the pressure sense port. For at least these reasons claim 1 is patentable over Brockway '191, Picha, or their combination, as are dependent claims 2-4, 7-9, 12-21, and 36.

The Office Action acknowledges that Brockway '191 does not disclose a surface modification to promote tissue in-growth. The Office Action contended that it would be obvious to place the Twardowski cuff at the distal end of the Brockway '191 catheter. Applicants disagree. Twardowski discloses a system that is not fully implantable, and instead uses a catheter that originates outside of the body, enters the body through the skin, passes through a catheter tunnel and into the jugular or left subclavian vein. Cuffs are used in the catheter tunnel near the skin entry point to stabilize the catheter in the tunnel. Neither Twardowski nor Brockway '191 discloses or suggests a surface modification on an outside surface of the distal portion of the catheter, the surface modification configured to promote tissue in-growth at a blood interface, wherein the surface modification comprises a layer of material comprising a tube that does not cover the port, wherein the tube is bonded to an external surface of the distal portion of the catheter by an adhesive that provides a transition from the surface modification tube to the external surface of the distal portion of the polyurethane catheter to reduce thrombus formation at the interface. Indeed, none of the references of record recognize the need for encouraging tissue in-growth at a blood interface where a distal portion of the catheter enters a vessel to facilitate healing to prevent thrombosis. Applicants' claimed device facilitates a controlled healing response whereby tissues grows into a surface modification tube at the blood interface but then stops growing-in across a transition provided by an adhesive bond from the

tube to an external surface of the distal portion of the catheter. These advantages are not contemplated by the references of record. For at least these reasons claim 1 is patentable over Brockway '191, Twardowski, or their combination, as are dependent claims 2-4, 7-9, 12-21, and 36.

Accordingly, Applicants request withdrawal of the Section 103 rejections of claims 1-4, 7-9, 12-18, 20-21, and 36.

Claim 37

Claim 37 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over various references. Applicants have amended claim 37 to depend from independent claim 1. The references cited in rejecting claim 37 do not cure the deficiencies of the references cited in the claim 1 rejection, and thus claim 37 is patentable for at least the reasons discussed above with reference to claim 1. Accordingly, Applicants request withdrawal of the Section 103 rejection of claim 37.

Claims 26 and 29

Claims 26 and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over various references. Applicants have amended each of claims 26 and 29 to depend from independent claim 1. The references cited in rejecting claims 26 and 29 do not cure the deficiencies of the references cited in the claim 1 rejection, and thus each of claims 26 and 29 is patentable for at least the reasons discussed above with reference to claim 1. Accordingly, Applicants request withdrawal of the Section 103 rejections of claims 26 and 29.

Claim 24

Claim 24 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,160,448 to Jackson ("Jackson") in view of Brockway '191. Applicants have amended claim 24 to clarify that a surface of the tube that comprises the catheter both defines the lumen through the catheter and encloses the distal end of the catheter. The amendment adds no new matter and is fully supported by the original specification (e.g., at FIG. 5S and paragraphs [0065] - [0066]).

Claim 24 is patentable over Jackson and Brockway '191, whether alone or in combination, because the references fail to disclose or suggest an implantable pressure sensing device that includes, *inter alia*, "a pressure transmission catheter having an open proximal end, a closed distal end, and a liquid-filled lumen extending therethrough, the proximal end of the catheter connected to the pressure sensor, wherein the catheter comprises a tube, and wherein a surface of the tube defines the lumen and encloses the distal end of the catheter."

In contrast, Jackson discloses a cannula with a balloon secured about the periphery of the distal end of the cannula. *See* Fig. 5; col. 2, lns. 10-14, 28-31. In Jackson's device, a surface of the cannula defines a lumen through the cannula, but that surface does not enclose the cannula's distal end. Rather, the balloon is secured about the periphery of the cannula so that a surface of the balloon encloses the cannula's distal end. At no point does Jackson disclose or suggest a tube having a surface that both defines a lumen through the tube and encloses the distal end of the tube.

For at least these reasons, claim 24 is patentable over the references of record, and Applicants request the removal of the Section 103 rejection to this claim.

CONCLUSION

Applicants submit that each of claims 1-4, 7-9, 12-21, 24, 26, 29, 32-34, 36, 38, and 41 is in condition for allowance, and request that the Examiner issue a notice of allowance.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, objection, issue or comment does not signify agreement with or concession of that rejection, objection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Please charge deposit account 06-1050 in the amount of $245 for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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